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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,213	07/07/2003	William E. Bay	1946/1G906-US2	8060
7590 DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022		EXAMINER DESAI, RITA J		
		ART UNIT 1625	PAPER NUMBER PAPER	
		MAIL DATE 08/24/2007	DELIVERY MODE PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/615,213	BAY ET AL.
	Examiner	Art Unit
	Rita J. Desai	1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on 05 June 2007.
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 29, 62, 63 and 65-70 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) 29 is/are allowed.
- 6)  Claim(s) 62, 63 and 65-70 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some \* c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/07.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims pending 29,62-63, 65-70.

Claims 67-70 are new.

The rejection of claims 29,62 and now new claims 67-70 under 35 USC 103 over WO 96/30036 in view of WO 97/36480, US 5,773,647 and WO 95/28838 and US 4757,066 has been withdrawn . Yes applicants do have some data to indicate that the di sodium salt has 4 times better delivery ability. The specifications teaches the calcitonin and as such has support for the same.

The rejection of the claims 29, 62-66 ( now 62,63,65-70) under written description has been partially withdrawn. The rejection still stands with respect to claims 62,63, 65-70.

The specifications just has the terms human growth hormones, recombinant human growth hormones , parathyroid hormone and fragments of parathyroid hormones without any specific definitions . Applicants argue that the different human growth hormones, recombinant human growth hormones , parathyroid hormone and fragments of parathyroid hormones are given in the various other patents. First off all that which is pertinent to the claims cannot be incorporated with reference, second there are no examples as to the “pharmaceutical” activity of all the various “active” agents.

None of this has been described in the specifications.

One of skill in the art would have to experiment to use the scope of the invention.

Thus the rejection still stands.

***Conclusion***

Claims 62, 63, 65-70 are rejected.

Claim 29 may be allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai  
Primary Examiner  
Art Unit 1625



R.D.  
August 18, 2007